DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2015

Biomet Microfixation
Ms. Lauren Jasper
Global Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K142823
Trade/Device Name: Biomet Microfixation Thoracic Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: January 16, 2015
Received: January 20, 2015

Dear Ms. Jasper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K142823

Device Name: Biomet Microfixation Thoracic Fixation System

Indications for Use: The Biomet Microfixation Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone to promote union.

Prescription Use __xx_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Prepared February 23, 2015

Submitter: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218

Contact: Lauren Jasper, Senior Regulatory Affairs Specialist
lauren.jasper@biomet.com
Telephone: (904) 741-9259
Fax: (904) 741-9425

Device Name: Biomet Microfixation Thoracic Fixation System

Device Classification:

Product Code	Device Name	Device Classification	Regulation Number	Regulation Description
HRS	Plate, Fixation, Bone	2	888.3030	Single/multiple component metallic bone fixation appliances and accessories

Indications for Use: The Biomet Microfixation Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone to promote union.

Contraindications: 1. Spanning a midline sternotomy; 2. Active infection; 3. Foreign body sensitivity, where material sensitivity is suspected, testing is to be completed prior to implantation; 4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

Device Description: The Biomet Microfixation Thoracic Fixation System is composed of metallic locking bone plates and locking screws that provide rigid fixation to fractures and osteotomies of the chest wall. These implants are available in multiple sizes and manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V).

Predicate Devices:
K121302, Biomet Microfixation Sternal Closure System
K133616, Synthes MatrixRIB Plating System

Similarities to Predicate Devices: The predicate and subject devices are metallic implants intended to be used for the fixation of bone in the thoracic anatomy. All implant systems consist of locking plates and locking screws to achieve rigid fixation of bone.

The subject device is indicated for use in the chest wall and sternum. The Biomet Microfixation Sternal Closure System is indicated for use in the anterior chest wall and sternum; the Synthes MatrixRIB Plating System is indicated for use in the ribs, sternum, and chest wall.

The subject device is manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V); the same materials as the Biomet Microfixation Sternal Closure System.

Differences to Predicate Devices: The subject devices consist of locking plates and locking screws. The Synthes MatrixRIB Plating System consists of locking plates, locking screws, and additionally, intramedullary splints.

The subject device is manufactured from Commercially Pure Titanium and Titanium Alloy (Ti-6Al-4V). The Synthes MatrixRIB Plating System is manufactured from Titanium Alloy; however, the composition of this alloy is Ti-6Al-7Nb.

Non-Clinical Performance Data: Non-clinical testing was not necessary for the determination of substantial equivalence.

Clinical Performance Data: Clinical testing was not necessary for the determination of substantial equivalence.

Sterilization Information: The implants are provided non-sterile to be sterilized by the end user.

Substantial Equivalence: The proposed devices have the same intended use as the predicate devices. The submission demonstrates that (1) any differences in technological characteristics of the predicates do not raise any new questions of safety and efficacy and (2) the proposed devices are at least as safe and effective as the predicates. It is concluded that the information included in this submission supports substantial equivalence.